

**RESPONSE UNDER 37 CFR 1.116**  
**EXPEDITED PROCEDURE - EXAMINING GROUP 1600**  
**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Jeffery R. Raymond et al.  
Application No. : 10/825,084  
Filed : April 15, 2004  
For : INDENE DERIVATIVES AS PHARMACEUTICAL AGENTS  
Examiner : Barbara P. Badio  
Art Unit : 1612  
Docket No. : 310151.412  
Date : October 10, 2008

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Alexandria, VA 22313-1450

Commissioner for Patents:

**RESPONSE UNDER 37 CFR 1.116**

This is in response to the Office Action dated July 11, 2008. Claims 1-29 are pending. Claims 5, 6, 9-21 and 24-29 are withdrawn from consideration as being directed to non-elected subject matter. Reconsideration of the claimed subject matter is respectfully requested in view of the following remarks.

**Previous Rejection of Claims 1 and 22 under 35 U.S.C. § 112**

Applicants acknowledge the withdrawal of the previous rejection of Claims 1 and 22 under 35 U.S.C. 112, ¶ 2.

**Previous Rejection of Claims 1-4, 7, 22 and 23 under 35 U.S.C. 102(b) in view of DE 1,084,718**

Applicants acknowledge the withdrawal of the previous rejection of Claims 1-4, 7, 22 and 23 under 35 U.S.C. 102(b) in view of DE 1,084,718 (Lettre et al.).

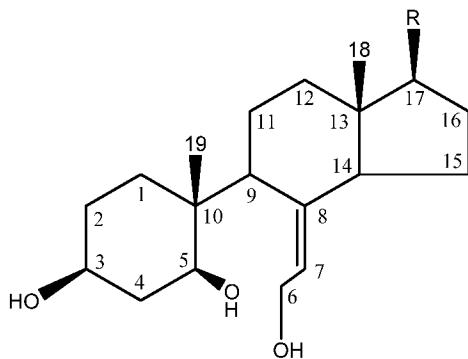
Previous Rejection of Claims 1-4, 22 and 23 under 35 U.S.C. 102(b) in view of JP 1,290,624

Applicants acknowledge the withdrawal of the previous rejection of Claims 1-4, 22 and 23 under 35 U.S.C. 102(b) in view of JP 1,290,624 (Oshida).

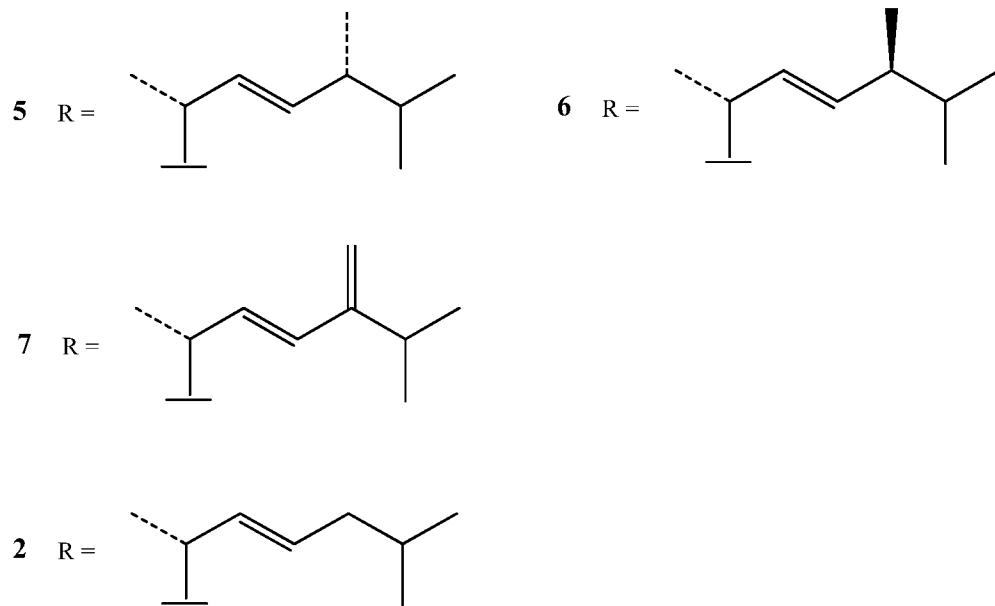
New Rejection of Claims 1-4, 22 and 23 under 35 U.S.C. 102(b)

The Examiner has newly rejected Claims 1-4, 22 and 23 under 35 U.S.C. 102(b) as being anticipated by the disclosure of Madaio, A. *et al.*, *Journal of Natural Products* (1990), Vol. 53, No. 3, pp. 565-572 (Madaio *et al.*). In particular, the Examiner contends that:

*Madaio et al. teaches 5,6-secosterols isolated from marine sponge (see the entire article). The reference teaches MeOH-H<sub>2</sub>O extracts of compounds such as:*



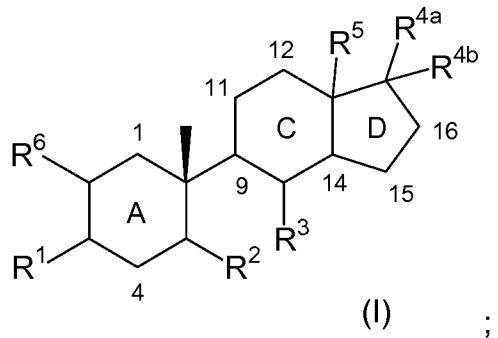
wherein R is:



(see structures on page 566; page 570, 2nd paragraph). The compounds and compositions taught by the reference are encompassed by the instant claims.

Applicants respectfully traverse this rejection for the following reasons:

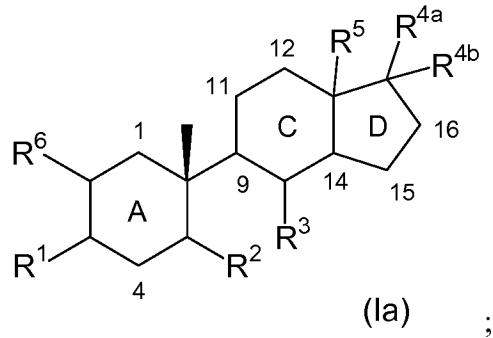
Claim 1 is directed to compounds of formula (I):



wherein  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^{4a}$ ,  $R^{4b}$ ,  $R^5$ ,  $R^6$  are as defined therein, as previously amended. In particular,  $R^3$  can be, *inter alia*,  $-R^8-OR^7$  where  $R^8$  can be an alkenylene chain and  $R^7$  can be hydrogen.

Claim 22 is directed to pharmaceutical compositions comprising a compound of formula (I).

Claims 2-4 are directed to compounds of formula (Ia):



wherein  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^{4a}$ ,  $R^{4b}$ ,  $R^5$ ,  $R^6$  are as defined therein, as previously amended. In particular,  $R^3$  can be, *inter alia*,  $-R^8-OR^7$  where  $R^8$  can be an alkenylene chain and  $R^7$  can be hydrogen.

Claim 23 is directed to pharmaceutical compositions comprising a compound of formula (Ia).

An "alkenylene chain" is defined in the specification, as originally filed, as follows:

*"Alkenylene" and "alkenylene chain" refer to a straight or branched divalent hydrocarbon chain linking the rest of the molecule to a radical group, consisting solely of carbon and hydrogen, containing at least one double bond and having from two to seven carbon atoms, e.g., ethenylene, propenylene, n-butenylene, and the like. The alkenylene chain is attached to the rest of the molecule through a single bond and to the radical group through a double bond or a single bond. The points of attachment of the alkenylene chain to the rest of the molecule and to the radical group can be through any two carbons within the chain. (Emphasis added)*

The "rest of the molecule" with respect to the R<sup>3</sup> substituent in the compounds of the invention is the "C" ring.

Accordingly, when R<sup>3</sup> is -R<sup>8</sup>-OR<sup>7</sup>, the -R<sup>8</sup>-OR<sup>7</sup> group is attached to the "C" ring through a single bond.

In contrast, the compounds disclosed in Madaio *et al.* all contain a substituent at the position corresponding to R<sup>3</sup> in the compounds of formula (I) and formula (Ia) which is attached to the ring corresponding to the "C" ring in the compounds of formula (I) and formula (Ia) through a double bond.

In view of the above remarks, and given that the claims must be read in light of the specification, Applicants respectfully submit that the disclosure of Madaio *et al.* does not anticipate the compounds set forth in Claims 1-4, 22 and 23. Applicants therefore respectfully request the withdrawal of the rejection of these claims under 35 U.S.C. 102(b) in view of Madaio *et al.*

#### Claim Objections

The Examiner has objected to Claims 7 and 8 as being dependent upon a rejected base claim. Applicants respectfully submit that this objection should be rendered moot when the above rejection is withdrawn.

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Favorable consideration of pending Claims 1-4, 7-8 and 22-23 in view of the foregoing remarks and issuance of an early Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,  
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